HUMAN HEALTH

ENVIRONMENTAL HEALTH

EARLIER DETECTION FOR A HEALTHIER FUTURE

GSP® Newborn screening system - the most advanced system for screening NBS disorders

Brochure for distribution in the US

PerkinElmer®
For the Better

GSP – THE MOST ADVANCED SOLUTION FOR SCREENING NBS DISORDERS

Every life is exceptional and every child is unique.
That's why your screening program should deliver
exceptional performance when it matters most
– at the beginning of a child's life.

As the most advanced platform for screening of NBS disorders, the GSP Newborn screening system offers outstanding screening accuracy and reliability, coupled with high efficiency and user-friendliness. It brings the future of neonatal screening to your laboratory, helping you provide children with a healthier start to life.

WHAT MAKES THE GSP AN ALL-IN-ONE SCREENING SYSTEM

- ☑ Fully automated from plate loading to results output
  - reduced hands-on stages and reduced risk of error
- ☑ Reliable dried blood spot measurement with several control steps
  - designed for DBS measurement
- ☑ Advanced data management solution
  - combines outstanding efficiency with reliable, quality controlled results
- ☑ Intuitive interface design and easy-to-learn functionalities
  - less time on training and workflow management
- ☑ Widest selection of neonatal assays
  - high accuracy and confidence in results
- ☑ Continuous sample and reagent loading
  - all analytes can be run together in any preferred order

THE GSP INSTRUMENT. AN ANALYZER LIKE NO OTHER.

WHAT THE GSP INSTRUMENT CAN DO FOR YOUR SCREENING PROGRAM

More flexible workflow
The GSP instrument is optimized for continuous sample loading. The loaded plates are processed automatically or users can prioritize the order in which plates are processed.

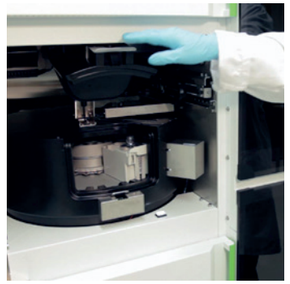
Reduced risk of error
Plates, reagents, QC materials and lot specific QC certificate information are all barcoded to support improved traceability and ease of use.

Safer and more convenient
GSP can be connected directly to a deionized water supply and waste line, so you no longer need to add water and drain the waste. The cooled reagent compartment also eliminates the need to unload reagents after assay runs and improves screening accuracy.

Laboratory friendly
The GSP instrument is easy for laboratory staff to learn to use, and is controlled via an intuitive touch-screen interface. The instrument requires minimal user training and supports effective staff rotation.

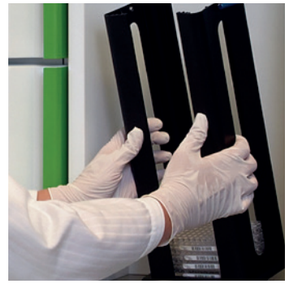
Improved results management
The GSP Workstation software tracks your laboratory workflow effectively, so you obtain reliable, quality controlled results with maximum efficiency.

USER-FRIENDLY AT EVERY STAGE



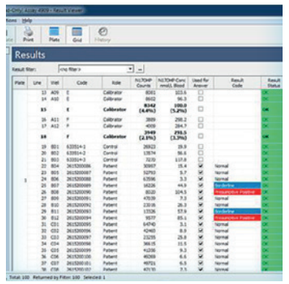
1 LOAD REAGENTS
Load bulk reagents and kit reagents as needed. It is not necessary to work out in advance the estimated use of reagents, since they can be loaded in excess or added whenever they run low.

2 PREPARE WORKLIST
If the worklist has not been generated automatically by the punching device, you can create it using GSP Workstation running on an adjacent computer



3 LOAD PLATES
Load a magazine with plates into the input stacker and an empty magazine into the output stacker. The instrument will start the assay runs automatically

4 CHECK STATUS
The touch screen allows you to prioritize the running order of your plates as you wish and see instantly the status of your assays, consumables, reagents and waste capacity.



5 VIEW RESULTS
When the assay is complete results are delivered to you at the GSP Workstation computer. You can check the calibration curve, quality control levels, possible notifications about the run, accept the assay and export and print results.

For a more detailed description, please check out the step-by-step GSP training video at **https://perkinelmeremea.box.com/GSP-training-video**

BEST-IN-CLASS INFORMATICS

THE GSP WORKSTATION COMPRISES FOUR MODULES, EACH DESIGNED TO IMPROVE WORKFLOW EFFICIENCY AND QUALITY MANAGEMENT.

1. KITLOT EDITOR

Kitlot Editor is an easy way to enter kitlot information. It also allows to edit cut-off limits and build reference curves from existing calibration curves. You can also edit default plate maps by changing sample or control definition.

2. PLATE GENERATOR

Plate Generator can be used to generate worklists if they are not generated directly through connected punchers.

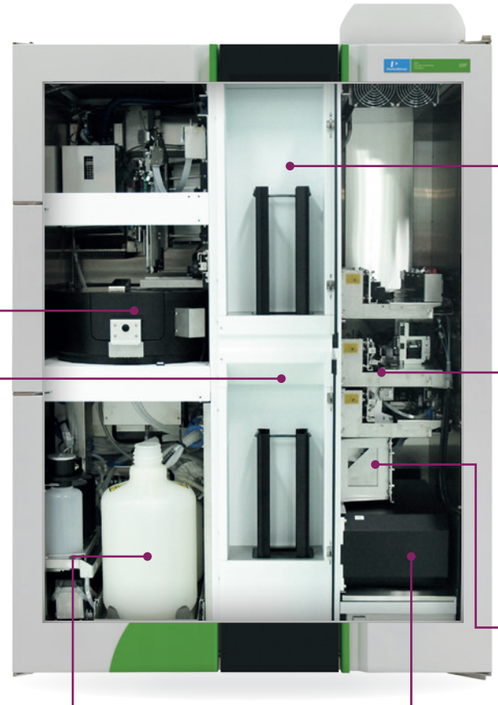
3. RESULT VIEWER

Result Viewer allows you to browse assay runs and related data in plate or worksheet formats. The screen layout can be customized to meet your laboratories' specific requirements.

4. QUALITY CONTROL PROGRAM

Quality Control Program supports effective long-term management and follow-up of quality control data. Store and graphically review results for the controls and monitor the level of a quality control sample. You can also specify quality control run definitions and materials, as well as QC multirules.

FUNCTIONAL VERSATILITY. FROM TOP TO BOTTOM.



Cooled reagents storage

- Temperature controlled storage for assay reagents
- Room for 13 reagent cassettes
- Enables continuous loading

Stacker modules

- Modules used to load plates to GSP and unload them after completion of the assays
- Each stacker can hold up to 26 plates

Liquid module

- Prepares Wash solution from the Wash concentrate
- Handles the waste solutions

Plate Manipulator

- "Elevator" for transferring plates between different modules of the GSP
- Forms the body of the instrument

Disk remover, washer and bulk dispenser

Incubator and Shakers

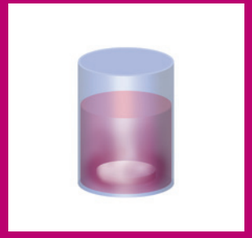
- Heated incubator operates at 37°C and can hold up to 12 plates
- Three non-heating shakers can each hold up to 6 plates

Measurement module

- xy-conveyer to move the plate under the measurement head
- Enables time resolved fluorescence, prompt fluorescence and absorbance measurements

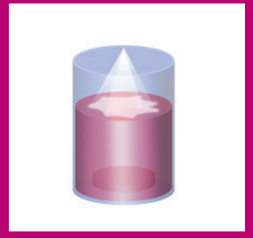
DESIGNED FOR DBS MEASUREMENT

GSP is designed to measure reliably dried blood spot samples by using several control steps. The used control steps are specified in the assay protocol. In case a control step is not passed, a notification message is reported.



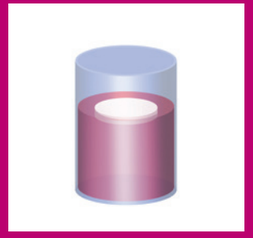
1. Elution control

Detects missing sample or poorly eluted disks in the wells. In case a missing disk is suspected, a notification message is reported.



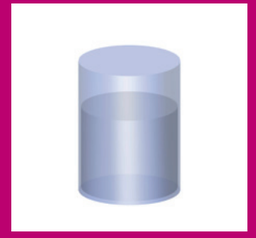
2. New measurement technology

New measurement step avoids outliers caused by unspecific fluorescence and reduces variation in results.



3. Floating disk control

Detects floating disks that may influence screening results.



4. Disk detection

Detects the removal of disks in DELFIA assays from the wells before measurement.

COMPLETE SOLUTION. EXCEPTIONAL ADVANTAGES.

HOW GSP CAN HELP INTEGRATE YOUR ENTIRE SCREENING PROCESS

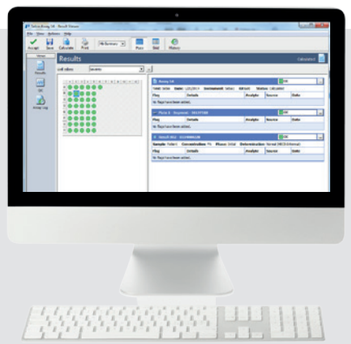
Neonatal screening is a highly complex workflow involving numerous process stages and continuous attention to quality control. Each link in the screening process must be as reliable and efficient as the next one.

By combining the GSP Newborn screening system with other PerkinElmer products, you can manage your entire screening program, from sample preparation and collection to analysis and results management.

NBS DISORDERS SCREENED BY THE GSP SYSTEM IN THE US

- Congenital Hypothyroidism
- Galactosemia
- Congenital Adrenal Hyperplasia
- Cystic Fibrosis
- Biotinidase deficiency

Learn more at **https://perkinelmeremea.box.com/NBS-today**



The devices shown here are available as standalone products. When interfaced, the devices together offer optimum screening performance and efficiency.

PERKINELMER HAS AN ANSWER TO EVERY STAGE IN THE SCREENING PROCESS

1 SAMPLE COLLECTION AND PREPARATION

PerkinElmer 226 Sample Collection Device is a 100% pure cotton linter filter paper optimized for DBS sampling.

When combined with Panthera-Puncher™9 or DBS Puncher you will get automatic worklist generation and transfer to GSP.

2 ANALYSIS AND MEASUREMENT

The GSP instrument is the device of choice for medium to large laboratories. It uses several measurement techniques for screening of NBS disorders and it supports the widest range of analytes and assay techniques.

The GSP workstation software is designed to follow laboratory workflows to obtain reliable, quality controlled results with maximum efficiency.

3 RESULT MANAGEMENT AND REPORTING

SpecimenGate® is PerkinElmer's dedicated informatics solution for newborn screening laboratories.

- Connects punchers and analysis instruments seamlessly and gathers results into one database
- Enables punchers to identify specimen-specific requests and responds accordingly (Smart Positive ID)
- Historical result-based cutoff values (Cutoff analyzer)
- Demographic-based cutoffs (latter requires Screening Center)

COMPLETE RANGE. BETTER SCREENING.

GSP Neonatal kits are the industry standard for analytical performance and reliability. Each kit includes reagents, QC material and specific QC certificates. Barcoding reduces the risk of errors, and all calibrators and controls come in dried blood spot format.

Automation and environmental controls ensure that screening accuracy is clearly improved when compared with manual assays. This also reduces the need for additional sample runs and allows for more effective use of laboratory resources.

GSP NEONATAL KITS SPECIFICATIONS

	GSP TSH	GSP T4	GSP 17-OHP	GSP IRT	GSP BTD	GSP TGAL	GSP GALT
Technology	DELFIA				Combination of DELFIA and Enzymatic	Enzymatic	
Assay duration	4 h 9 min	2 h 56 min	3 h 56 min	2 h 43 min	4 h 13 min	1 h 33 min	2 h 50 min
On board stability	14 days	14 days	14 days	14 days	14 days	7 days	48 hours
Measuring range	1.31 µU/mL blood (2.91 µU/mL serum) - 250 µU/mL blood (555 µU/mL serum)	0.81 µg/dL blood (1.61 µg/dL serum) - 15 µg/dL blood (30 µg/dL serum)	1.2 nmol/L blood (0.9 ng/mL serum) - 300 nmol/L blood (220 ng/mL serum)	9 ng/mL blood (20 ng/mL serum) - 500 ng/mL blood (1110 ng/mL serum)	14.8-325 U/dL	64-2775 µmol/L blood (1.15-50 mg/dL)	2.5-25 U/dL blood
Fully automated	✓	✓	✓	✓	✓	✓	✓
Calibrators and Controls in DBS format	✓	✓	✓	✓	✓	✓	✓
Elution control	✓	✓	✓	✓	✓	✓	✓
New measurement technology	*	*	*	*	*	✓	*
Floating disk control	*	*	*	*	*	*	✓
Disk detection control	✓	✓	✓	✓	✓	*	*
Reagents, plates and QC materials barcoded	✓	✓	✓	✓	✓	✓	✓
24 hrs valid calibration curve	✓	✓	✓	✓	✓		✓
Reagents ready-to-use	✓	✓	✓	✓	✓	2 reconstitution steps	1 reconstitution step
FDA registered	✓	✓	✓	✓	✓	✓	✓
Plates included	✓	✓	✓	✓	✓	Prod. No. 4091-0010	Prod. No. 4076-0010

* The measurement /control step is not required for the specific assay

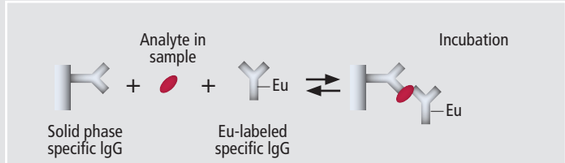
For Congenital Hypothyroidism
GSP NEONATAL hTSH KITS

The PerkinElmer GSP Neonatal hTSH assay is used with dried blood spot specimens as an aid in screening newborns for congenital hypothyroidism.

- Sensitive, robust DELFIA chemistry for confidence in results
- Incubation time only 3.5h

THE GSP NEONATAL hTSH ASSAY

The GSP Neonatal hTSH assay is based on a direct sandwich technique where two monoclonal antibodies recognize separate antigenic determinants on the hTSH molecule. The fluorescence signal is proportional to the analyte concentration in the sample.



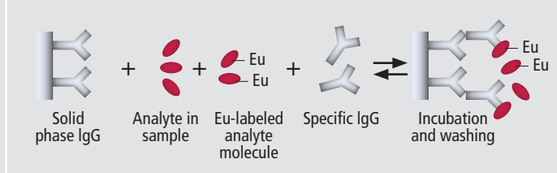
For Congenital Hypothyroidism
GSP NEONATAL THYROXINE (T4) KITS

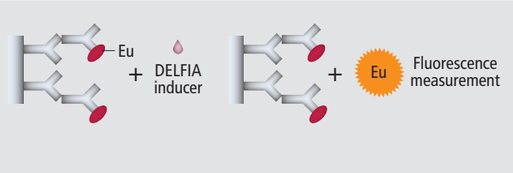
The PerkinElmer GSP Neonatal Thyroxine (T4) assay is used with dried blood spot specimens as an aid in screening newborns for congenital hypothyroidism.

- Sensitive, robust DELFIA chemistry for confidence in results
- Incubation time only 2h

THE GSP NEONATAL THYROXINE T4 ASSAY

In the GSP Neonatal Thyroxine (T4) assay the analyte competes with europium-labeled T4 for the binding sites on T4 specific monoclonal antibodies and the fluorescence signal is inversely proportional to the analyte concentration in the sample.





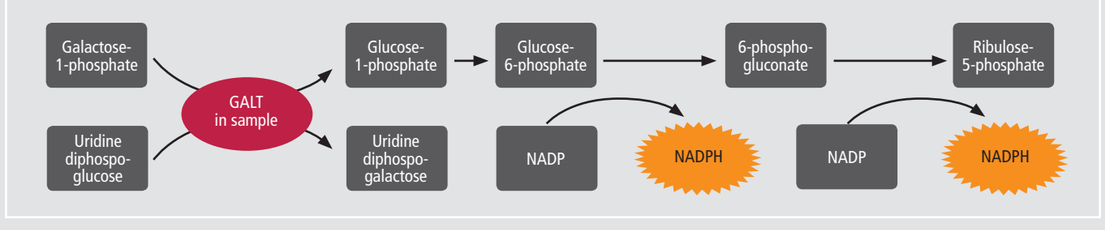
For Galactosemia
GSP NEONATAL GALT KIT

This kit is intended for the semi-quantitative determination of galactose-1-phosphate uridyl transferase (GALT) activity in blood specimens dried on filter paper as an aid in screening newborns for classical galactosemia caused by GALT deficiency using the GSP instrument.

- Faster assay – incubation time now only 2 h
- Provides results in today's preferred unit, U/dL blood
- Floating disks control

THE GSP NEONATAL GALT ASSAY

In the GSP Neonatal GALT assay, GALT in the blood sample catalyzes a reaction between galactose- 1-phosphate and uridine diphosphoglucose contained in the assay substrate reagent. In the course of further reactions NADP is reduced to NADPH, a fluorescent substance that can be measured with excitation at 355 nm and emission detection at 460 nm.



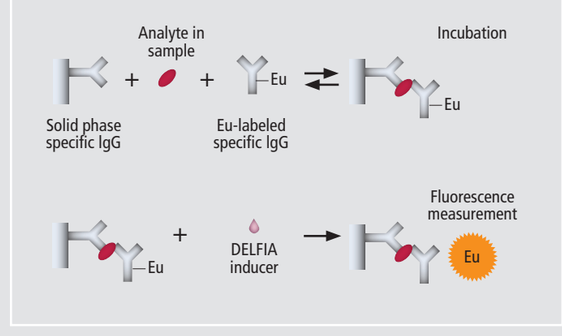
For Cystic Fibrosis
GSP NEONATAL IRT KIT

This kit is intended for the quantitative determination of human immunoreactive trypsin(ogen) (IRT) in blood specimens dried on filter paper as an aid in screening newborns for cystic fibrosis using the GSP instrument.

- Sensitive, robust DELFIA chemistry for confidence in results
- Linear curve fitting- improved precision
- Incubation time 2h

THE GSP NEONATAL IRT ASSAY

The assay is based on a direct sandwich technique where two monoclonal antibodies bind to different epitopes on the target molecule. The fluorescence signal is proportional to the analyte concentration in the sample.



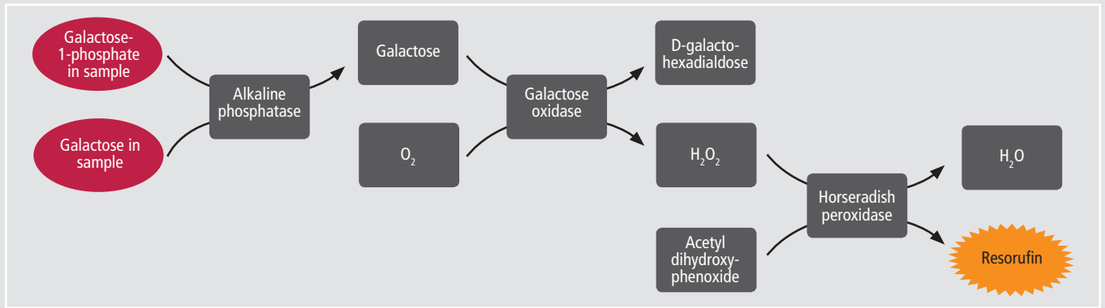
For Galactosemia
GSP TOTAL GALACTOSE KIT

This kit is intended for the quantitative determination of total galactose (galactose and galactose-1-phosphate) concentrations in blood specimens dried on filter paper as an aid in screening newborns for galactosemia using the GSP instrument.

- The first fully automated Total Galactose assay for galactosemia screening
- The reconstituted reagent stability is improved from one hour in the manual kit to several days
- Resorufin step added for improved performance

THE GSP NEONATAL TOTAL GALACTOSE (TGAL) ASSAY

The GSP Neonatal Total Galactose kit makes use of a fluorescent galactose oxidase method. The assay measures total galactose, i.e. both galactose and galactose- 1-phosphate. The fluorescence is measured using an excitation wavelength of 505 nm and an emission wavelength of 580 nm.



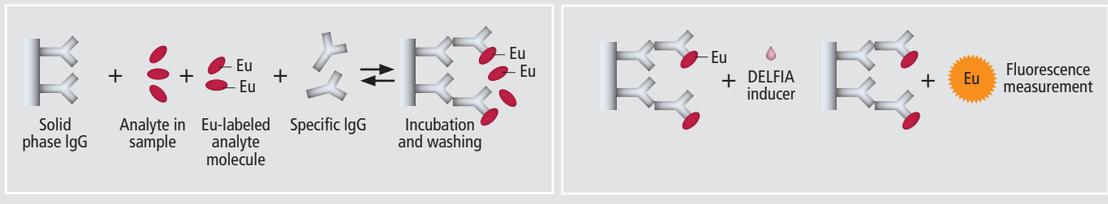
For Congenital Adrenal Hyperplasia
GSP NEONATAL 17α-OH-PROGESTERONE KIT

This kit is intended for the quantitative determination of human 17α-OH-progesterone in blood specimens dried on filter paper as an aid in screening newborns for congenital adrenal hyperplasia (CAH) using the GSP instrument.

- Sensitive, robust DELFIA chemistry for confidence in results
- Incubation time 3h

THE GSP NEONATAL 17α-OH-PROGESTERONE ASSAY

The GSP Neonatal 17α-OH-progesterone assay is based on the competitive binding of europium-labeled 17OHP and 17OHP in the sample to 17OHP-specific antibodies. The fluorescence signal is inversely proportional to the analyte concentration in the sample.



For Biotinidase deficiency

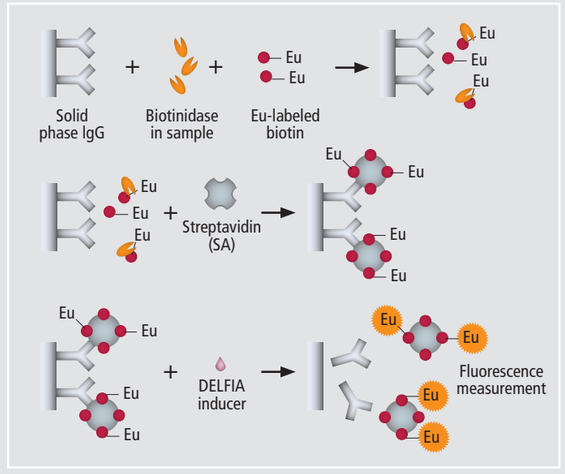
GSP NEONATAL BIOTINIDASE KIT

This kit is intended for the quantitative determination of human biotinidase activity in blood specimens dried on filter paper as an aid in screening newborns for biotinidase deficiency using the GSP instrument.

- The first fully automated assay for biotinidase deficiency
- All reagents ready-to-use

THE GSP NEONATAL BIOTINIDASE ASSAY

The Neonatal Biotinidase assay combines an enzyme reaction with a solid phase time-resolved immunofluorescence assay. The amide bond in EU-labeled biotin is cleaved by the biotinidase present in the sample. The enzyme reaction is stopped by addition of streptavidin and the formed streptavidin-biotin complexes are captured by the solid phase monoclonal antibodies. DELFIA® Inducer dissociates the molecules into the solution where the europium fluorescence is measured. The measured fluorescence is inversely proportional to the biotinidase activity of the sample.



INSTRUMENT SPECIFICATIONS

Physical dimensions	Height Width Depth Weight	1960 mm (77.2") 1310 mm (51.6") 760 mm (30.0") 610 kg (1345 lb)		
Power requirements	Power consumption Mains voltage	1500 VA 100 - 240 V, 50 - 60 Hz		
Environmental conditions	Operating Temperature Temperature range Temperature range	18 - 30 °C 18 - 27 °C 28 - 30 °C	 Relative humidity Relative humidity	 10 – 80 % 10 – 65 %
Noise	< 60 dB			
The water used for preparing wash solution and for rinsing has to be deionized.				
Samples	Sample type Sample identification	Blood disks from dried blood spots punched into 96-well plates Barcode reader or keyboard input		
Loading	Continuous sample loading Continuous reagent loading Continuous bulk reagent loading			
Bulk Reagents				
Washing and rinsing	Wash solution Rinse water	Automatic dilution of Wash concentrate from a mains water line (deionized) or from an external bottle outside the instrument Automatic filling from a mains water line (deionized) or from an external bottle outside the instrument		
Liquid waste	Waste capacity	Automatic disposal if connected to a waste line OR manual disposal 16 L (15 plates)		

Performance specifications

Capacity	Sample capacity Reagent capacity Heated incubator module Shaking module Wash concentrate capacity Manual water filling or waste emptying Automatic water filling and waste emptying		26 plates (2496 wells) up to 13 reagent cassettes 12 plates 3 x 6 plates 2 liters 11 plates before user intervention required No restrictions
Low volume reagent pipette	Volume range Precision (CV%) Accuracy	5 - 50 µl < 1.5 % within ± 8 %	
High volume reagent pipette	Volume range Precision (CV%) Accuracy	25 - 200 µl < 1.5 % within ± 4 %	
Measurement unit	Measurement modes Signal with 1 nM Eu	TRF, FI, Abs 1 000 000 cps ± 17%	
Humidity	Plate storage area	< 60 %	
Temperature	Temperature inside the instrument Reagent storage temperature Heated incubator module		25 ± 2 °C 10 ± 2 °C 37 ± 1 °C

ORDERING INFORMATION

2021-0010 Genetic Screening Processor

The Genetic Screening Processor includes GSP instrument and GSP Workstation.

The GSP instrument includes:

High volume reagent tips (960)

Low volume reagent tips (960)

Cassette pack (3x) for tips and reagents, each containing:
- Reagent cassette (6x)
- Low volume tip cassette (1x)
- High volume tip cassette (1x)
- Waste tip cassette (1x)

Anti-evaporation caps (3 x 10)

Magazine for 25 plates, input / output (2x)

External barcode reader

External keyboard with touchpad

Installation kit containing necessary cables and tubing

Service kit containing parts for routine maintenance of the GSP instrument

User manual (English paper version and other available language versions on a CD)

Instrument manual (English)

2021-3010 GSP Workstation includes:

Computer with GSP Workstation software

GSP Workstation Quality Control manual (English paper version and other available language versions on a CD)

GSP Workstation Result Viewer, Kitlot Editor and Plate Generator manual (English paper version and other available language versions on a CD)

	Kits
3301-001U	GSP Neonatal hTSH kit
3302-001U	GSP Neonatal Thyroxine (T_4) kit
3303-001U	GSP Neonatal GALT kit
3305-001U	GSP Neonatal 17α-OH-progesterone kit
3306-001U	GSP Neonatal IRT kit
3307-001U	GSP Neonatal Biotinidase kit
3309-001U	GSP Neonatal Total Galactose kit

All the kits include reagents for 12 plates (1152 assays)

	Consumables
3304-0010	DELFIA Inducer
4080-0010	GSP Wash concentrate
4076-0010	Clear microplates for GSP Neonatal GALT kit

Products in this brochure may not be available in all countries. Confirm availability with your local PerkinElmer representative.

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ISO 9001
CMDCAS
ISO 14001
OHSAS 18001

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